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Attorney Docket No. 21415-0014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) Ranjeny THOMAS et al. Confirmation No. 1436

Appl. No.: 10/524,539 Examiner: Unassigned

Filing Date: February 14, 2005 Art Unit: Unassigned

Title: IMMUNOMODULATING COMPOSITIONS, PROCESSES FOR THEIR PRODUCTION AND USES THEREFOR

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56 and 37 CFR §1.97

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56 and §1.97. A copy of each of the listed documents are being submitted to comply with the provisions of 37 C.F.R. §1.97-1.99.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

The PTO did not receive the following listed item(s) one set of N.D./S

RELEVANCE

The relevance of the documents cited on the attached Form SB/08A are described in the present specification.

Document A129 was cited in an earlier Information Disclosure Statement filed by Applicants. Thus, no copy is being provided at this time.

These documents came to the Applicants' attention during a search of the corresponding international application. A copy of the International Search Report setting forth the portion of each reference considered relevant by the examiner is attached.

TIMING/FEE

The instant Information Disclosure Statement is being filed in compliance with 37 CFR §1.97(b) prior to the mailing date of the first official action, therefore, no fee is required in connection with its filing. However, the Commissioner is hereby authorized to charge any deficiency or to credit any overpayment to Deposit Account No. 08-1641.

Applicants respectfully request that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08A be returned in accordance with M.P.E.P. §609.

Respectfully submitted,



\_\_\_\_\_  
Date

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### OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

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	A01	Anton, D., Dabadghao, S., Palucka, K., Hoim, G. & Yi, Q. (1998). Generation of dendritic cells from peripheral blood adherent cells in medium with human serum. Scand J Immunol 47, 116-121	
	A02	Albert ML, Sauter B, Bhardwaj N. (1998). Dendritic cells acquire antigen from apoptotic cells and induce class I-restricted CTLs. Nature 392(6671), 86-89	
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	A06	Baldwin, A. S., Jr. (1996). The NF- $\kappa$ B and I $\kappa$ B proteins: new discoveries and insights, Annu Rev Immunol 14, 649-683	
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	A09	Battye, F.L. & Shortman, K. (1991). Flow cytometry and cell-separation procedures. [Review]. Curr. Opin. Immunol. 3, 238-241	
	A10	Bouchon, A., Facchetti, F., Weigand, M. A., and Colonna, M. (2001a). TREM-1 amplifies inflammation and is a crucial mediator of septic shock, Nature 410, 1103-1107	
	A11	Bouchon, A., Hernandez-Munain, C., Celia, M., and Colonna, M. (2001b). A DAP12-mediated pathway regulates expression of CC chemokine receptor 7 and maturation of human dendritic cells, J Exp Med 194, 1111-1122	

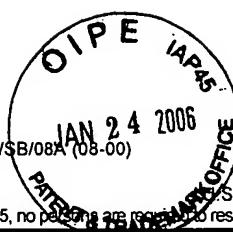
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	A12	Buhlmann, J. E., Foy, T. M., Aruffo, A., Crassi, K. M., Ledbetter, J. A., Green, W. R., Xu, J. C., Shultz, L. D., Roopesian, D., Flavell, R. A., and et al. (1995). In the absence of a CD40 signal, B cells are tolerogenic, <i>Immunity</i> 2, 645-653	
	A13	Burkly, L., Hession, C., Ogata, L., Reilly, C., Marconi, L. A., Olson, D., Tizard, R., Cate, R., and S Lo, D. (1995). Expression of RelB is required for the development of thymic medulla and dendritic cells, <i>Nature</i> 373, 531-536	
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	A20	Cobbold, S., and Waldmann, H. (1998). Infectious tolerance, <i>Curr Opin Immunol</i> 10, 518-524	
	A21	Corinti S, Medaglini D, Cavani A, Rescigno M, Pozzi G, Ricciardi-Castagnoli P, Girolomoni O. (1999). Human dendritic cells very efficiently present a heterologous antigen expressed on the surface of recombinant gram-positive bacteria to CD4+ T lymphocytes. <i>J Immunol</i> 163(6), 3029-3036	
	A22	Cottrez, F., Hurst, S. D., Coffman, R. L., and Groux, H. (2000). T regulatory cells I inhibit a Th2-specific response in vivo, <i>J Immunol</i> 165, 4848-4853	
	A23	Davis, L.S., McIlraith, M.J., Paecheo, T., Becker, B., Adix, L.M., Thomas, R., Wacholtz, M.C. & Lipsky, P.E. (1994). Assessment of a positive selection technique using an avidin column to isolate human peripheral blood T cell subsets. <i>J Immunol Meth</i> 175, 247-257	

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	A24	de Jong, E. C., Vieira, P. L., Kalinski, P., and Kapsenberg, M. L. (1999) Corticosteroids inhibit the production of inflammatory mediators in immature monocyte-derived DC and induce the development of tolerogenic DC3, <i>J Leukoc Biol</i> 66, 201-204	
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	A26	Dhodapkar, M. V., Steinnian, R. M., Krasovsky, J., Munz, C., and Bhardwaj, N. (2001). Antigen-specific inhibition of effector T cell function in humans after injection of immature dendritic cells, <i>J Exp Med</i> 193, 233-238	
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	A30	Fearnley, D.B., Whyte, L.F., Carnoutsos, S.A., Cook, A.H. & Hart, D.N. (1999). Monitoring human blood dendritic cell numbers in normal individuals and in stem cell transplantation. <i>Blood</i> 93, 728-736	
	A31	Feldmann, M. (2001). Pathogenesis of arthritis: recent research progress, <i>Nat Immunol</i> 2, 771-773	
	A32	Feldmann, M., and Maini, R. N. (2001). Anti-TNF $\alpha$ therapy of rheumatoid arthritis: What have we learned?, <i>Annu Rev Immunol</i> 19, 163-196	
	A33	Feuerstein, B., Berger, T.G., Maczek, C., Roder, C., Schreiner, D., Hirsch, U., Haendle, I., Leisgang, W., Glaser, A., Kuss, O., Diepgen, T.L., Schuler, G. & Schuler-Thummel, B. (2000). A method for the production of cryopreserved aliquots of antigen-preloaded, mature dendritic cells ready for clinical use. <i>J Immunol Methods</i> 245, 15-29	
	A34	Fleming, W.H., Mulcahy, J.M., McKearn, I.P. & Streeter, P.R. (2001). Progenipoitin-1: a multifunctional agonist of the granulocyte colony- stimulating factor receptor and fetal liver tyrosine kinase-3 is a potent mobilizer of hematopoietic stem cells. <i>Exp Hematol</i> 29, 943 - 951	
	A35	Freudenthal, P.S. & Steinman, R.M. (1990). The distinct surface of human blood dendritic cells, as observed after an improved isolation method. <i>Proc Natl Acad Sci U S A</i> 87, 7698-7701	

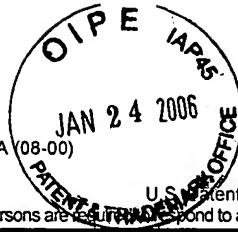
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	A36	Gao, J. X., Madrenas, J., Zeng, W., Cameron, M. J., Zhang, Z., Wang, I. J., Zhong, It, and Grant, D. (1999). CD40-deficient dendritic cells producing interleukin- 10, but not interleukin- 12, induce T-cell hyporesponsiveness in vitro and prevent acute allograft rejection. <i>Immunology</i> 98, 159-170	
	A37	Garderet, L., Cao, H., Salamero, J., Verge, V., Tisserand, E., Scholl, S., Gorin, N.C. & Lopez, M. 10 (2001). In vitro production of dendritic cells from human blood monocytes for therapeutic use. <i>J Hematother Stem Cell Res</i> 10, 553-567	
	A38	Geissmann, F., Prost, C., Monnet, J.P., Dy, M., Brousse, N. & Hermine, O. (1998). Transforming growth factor beta 1, in the presence of granulocyte/macrophage colony-stimulating factor and interleukin 4, induces differentiation of human peripheral blood monocytes into dendritic Langerhans cells, <i>J Exp Med</i> , 187, 961-966	
	A39	Giannoukakis, N., Bonham, C. A., Qian, S., Zhou, Z.. Peng, L., Harnaha, J., Li, W., Thomson, A. W., Fung, 3. J., Robbins, P. D., and Lu, L. (2000). Prolongation of cardiac allograft survival using dendritic cells treated with NP-kB decoy oligodeoxyribonucleotides, <i>Mol Ther</i> 1, 430-437	
	A40	Goodnow, C. C. (2001). Pathways for self-tolerance and the treatment of autoimmune diseases, <i>Lancet</i> 357, 2115-2121	
	A41	Gregori, S., Casorati, M., Amuchastegui, S., Smiroldo, S., Davalli, A. M., and Adorirri, L. (2001). Regulatory T cells induced by lalpha,25-dihydroxyvitamin d(3) and mycophenolate mofetil treatment mediate transplantation tolerance, <i>J Immunol</i> 167, 1945-1953	
	A42	Griffin, M. D., Lutz, W., Phan, V. A., Bachman, L. A., McKean, D. 3., and Kumar, R. (2001). Dendritic cell modulation by 1 alpha,25 dihydroxyvitamin D3 and its analogs: a vitamin D receptor-dependent pathway that promotes a persistent state of immaturity in vitro and in vivo, <i>Proc Natl Acad Sci USA</i> 98, 6800-6805	
	A43	Groopman, J.E., Mitsuyasu, R.T., DeLeo, M.J., Oette, D.H. & Golde, D.W. (1987). Effect of recombinant human granulocyte-macrophage colony-stimulating factor on myelopoiesis in the acquired immunodeficiency syndrome, <i>N Engl J Med</i> 317, 593-598	
	A44	Grouard, G., Risoan, MC., Filgueira, L., Durand, I., Banchereau, J. & Liu, Y.J. (1997). The enigmatic plasmacytoid T cells develop into dendritic cells with interleukin (IL)-3 and CD40-ligand <i>J Exp Med</i> 185, 1101-1111	
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	A46	Groux, H., O'Garra, A., Bigler, M., Rouleau, M., Antonenico, S., de Vries, J. E., and Roncarolo, M. G. (1997). A CD4+ T-cell subset inhibits antigen-specific T-cell responses and prevents colitis, <i>Nature</i> 389, 737-742	
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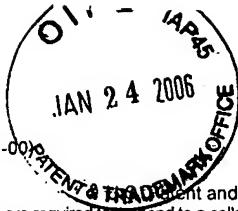
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	A48	Hacker, G., Redecke, V. & Hacker, H. (2002). Activation of the immune system by bacterial CpG-DNA. <i>Immunology</i> 105, 245-251	
	A49	Hackstein, H., MoreHi, A. E., Larregina, A. T., Ganster, R. W., Papworth, G. D., Logar, A. I., Watkins, S. C., Falo, L. D., and Thomson, A. W. (2001). Aspirin inhibits in vitro maturation and in vivo immunostimulatory function of murine myeloid dendritic cells, <i>J Immunol</i> 166, 7053-7062	
	A50	Hanninen, A., Martinez, N. R., Davey, G. M., Heath, W. R., and Han'ison, L. C. (2002) Transient blockade of CD40 ligand dissociates pathogenic from protective mucosal immunity, <i>J Clin Invest</i> 109, 261-267	
	A51	Hart DN. Fabre JW. (1981). Demonstration and characterization of Ia-positive dendritic cells in the interstitial connective tissues of rat heart and other tissues, but not brain. <i>J Exp Med</i> 154(2),347-361	
	A52	Hart DN, McKenzie IL. (1988). Isolation and characterization of human tonsil dendritic cells. I <i>Exp Med</i> 168(1), 157-170	
	A53	Hofer, S., Rescigno, M., Granucci, F., Citterio, S., Francolini, M., and Ricciardi-Castagnoli, P. (2001). Differential activation of NP-kappa B subunits in dendritic cells in response to Gram-negative bacteria and to lipopolysaccharide., <i>Microbes Infect</i> 3, 259-265	
	A54	Hill, A.D., Naama, H.A., Calvano, S.E. & Daly, J.M. (1995). The effect of granulocyte macrophage colony-stimulating factor on myeloid cells and its clinical applications. <i>J Leukoc Biol</i> 58, 634-642	
	A55	Hollander, G. A., Castigli, E., Kulbacki, R., Su, M., I\$urakoff, S. J., Gutierrez-Ramos, J. C., and Geha, R. S. (1996). Induction of alloantigen-specific tolerance by B cells from CD40- deficient mice, <i>Proc Natl Acad Sci U S A</i> 93, 4994-4998	
	A56	Huang, F. P., Platt, N., Wykes, M., Major, J. R., Powell, T. J., Jenkins, C. D., and MacPherson, G. G. (2000). A discrete subpopulation of dendritic cells transports apoptotic intestinal epithelial cells to T cell areas of mesenteric lymph nodes, <i>J Exp Med</i> 191,435-444	
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	A58	Kaisho, T. & Akira. S. (2002). Toll-like receptors as adjuvant receptors. <i>Biochern Biophys Acta</i> 1589, 1-13	
	A59	Kamath, A.T., Pooley, J., O'Keeffe, M.A., Vremec, D., Zhan, Y., Lew, A.M., D'Amico, A., Wu, L., Tough, D.F. & Shortman, K. (2000). The development, maturation, and turnover rate of mouse spleen dendritic cell populations. <i>J Immunol</i> 165, 6762-6770	

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Attorney Docket Number 21415-0014US

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Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A128	Wu, L., A. D. A., Winkel, K. D., Suter, M., Lo, D., and Shortman, K. (1998). RelB is essential for the development of myeloid-related CD8alpha- dendritic cells but not of lymphoid-related CD8alpha+ dendritic cells, <i>Immunity</i> 9, 839-847	
	A129	Yoshimura, S., Bondeson, J., Foxwell, B. M., Brennan, F. M., and Feldmann, M. (2001). Effective antigen presentation by dendritic cells in NF-kappaB dependent coordinate regulation of MHC, costimulatory molecules and cytokines, <i>Int Immunol</i> 13, 675-683	
	A130	Zheng, Z., Takahashi, M., Narita, M., Toba, K., Liu, A., Furukawa, T., Koike, T. & Aizawa, Y. (2000). Generation of dendritic cells from adherent cells of cord blood by culture with granulocyte-macrophage colony-stimulating factor, interleukin-4, and tumor necrosis factor-alpha. <i>J Hematother Stem Cell Res</i> 9, 453-464	
	A131	Zhou, P., and Seder, R. A. (1998). CD40 ligand is not essential for induction of type 1 cytokine responses or protective immunity after primary or secondary infection with histoplasma capsulatum, <i>J Exp Med</i> 187, 1315-1324	

Examiner Signature	Date Considered
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<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>2</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.